1633

OIPE JC93 APR 23 2001 PATENT & TRADEMARK OFFICE

TRANSMITTAL LETTER (General - Patent Pending)	Docket No. CEDAR 043453

In Re Application Of: Black et al.

Serial No.	Filing Date	Examiner	Group Art Unit
09/491,500	January 26, 2000	E. Sorbello	1633

Title:

METHOD FOR USING POTASSIUM CHANNEL AGONISTS FOR DELIVERING A MEDICANT TO AN ABNORMAL BRAIN REGION AND/OR A MALIGNANT TUMOR

RECEIVED
APR 25 2001
TECH CENTER 1600/2900

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith is:

Statement of the Substance of the Interview

in the above identified application.

- ☒ No additional fee is required.
- ☐ A check in the amount of is attached.
- ☒ The Assistant Commissioner is hereby authorized to charge and credit Deposit Account No. 50-1597 as described below. A duplicate copy of this sheet is enclosed.
  - ☐ Charge the amount of
  - ☒ Credit any overpayment.
  - ☒ Charge any additional fee required.

Signature

Dated: **APRIL 20, 2001**

Nisan A. Steinberg, Ph.D.
Registration No. 40,345
SIDLEY & AUSTIN
555 West Fifth Street
Los Angeles, CA 90013-1010
Ofc: 213/896-6665
Fax: 213/896-6600

I certify that this document and fee is being deposited on 04/20/01 with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Signature of Person Mailing Correspondence

ANN WEISS

Typed or Printed Name of Person Mailing Correspondence

cc:

P07 43453 (CEDAR)

#11 1308
4/26/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Black *et al.*

Serial No. 09/491,500

Filed: January 26, 2000

For: **METHOD FOR USING POTASSIUM CHANNEL AGONISTS FOR DELIVERING A MEDICANT TO AN ABNORMAL BRAIN REGION AND/OR A MALIGNANT TUMOR**

Examiner: Sorbello, E.

Art Unit: 1633

STATEMENT OF THE SUBSTANCE OF THE INTERVIEW

Assistant Commissioner for Patents
Washington, D. C. 20231

CERTIFICATE OF FIRST CLASS MAILING
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING FILED BY FIRST CLASS MAIL AND IS ADDRESSED TO THE ASSISTANT COMMISSIONER FOR PATENTS WASHINGTON, D. C. 20231, ON
April 20, 2001
BY _____
ANN WEISS
April 20, 2001
(DATE OF SIGNATURE)

Dear Sir/Madam:

This Statement of the Substance of the Interview is submitted in response to an Interview Summary provided by the Examiner, and mailed to Applicants on March 20, 2001. It is submitted in reference to a telephonic interview graciously granted by Examiner Eleanor Sorbello and Supervisory Patent Examiner Deborah J. R. Clark, on March 14, 2001, concerning the above-captioned application.

Although the Examiner's Interview Summary indicated that a separate record of the substance of the interview was not required from Applicants, Applicants have already summarized the substance of the entire interview in Applicants' Remarks in a Response to Office Action, which Applicants mailed on March 20, 2001. Further, Applicants have carefully reviewed the summary prepared by the Examiner and appreciate the Examiner's efforts to

recount the substance of the interview. Nevertheless, in reviewing the Interview Summary provided by the Examiner, Applicants have noted some inaccurate and incomplete statements, which Applicants now respectfully bring to the Examiner's attention.

With respect to the Examiner's Interview Summary, at page 3, second paragraph, Dr. Black stated that vasodilation and permeability were *not* obviously linked and that vasodilation and permeability were *independent* one from the other, *not* dependent. In the instant application, the claims are directed to increased permeability selectively to *abnormal* microvessels, due to the activation of K_{ATP} and K_{Ca} channels. Dr. Black pointed out later in the interview that that main difference and point, that was not noticed in two office actions regarding the Sobey reference, was that Sobey teaches that K_{Ca} channels will mediate the increased dilation of normal blood vessels, and that if vasodilation were the mechanism linked to increased vascular permeability, then normal as well as abnormal vessels would become more permeable by activation of K_{Ca} channels. But this is not the case. Therefore, this is further evidence that the mechanism of vasodilation, as taught by Sobey, is not linked to, and does not make obvious, increasing vascular permeability selectively in *abnormal* blood vessels, to which Applicants' invention is directed. Dr. Black reiterated that Applicants did not find increased *permeability* of capillaries in the entire brain, but only in the *abnormal* brain tissue.

Also, Applicants wish to point out that Dr. Black did in no way imply that the relatively greater quantities of K_{Ca} channels in abnormal tissue, compared to normal tissues, was influenced by the administration of the agonists, contrary to the implication of the Examiner's Interview Summary, but is rather a property of the abnormal vascular tissue, regardless of the administration of agonists.

With respect to the Examiner's Interview Summary, at page 3, fourth paragraph, as to Claims 108 and 109, Applicants note that Mr. Steinberg cited a number of cases, including, *In re Gulack,* 217 USPQ 401, 403, (Fed Cir. 1983), in support of allowability. Further, SPE-Clark stated with respect to Claims 108 and 109 that these claims would be allowable were Claims 108 amended to recite at its end something like "by increasing the permeability of a capillary or arteriole delivering blood to the cells of the abnormal brain region." Also, contrary

to the Examiner's Interview Summary, SPE Clark's reference to the possibility of redrafting as a Jepson claim was with respect to Claim 6, not claims 108 and 109.

With respect to the Examiner's Interview Summary, at page 3, sixth paragraph, as to Claims 6 and 23, SPE-Clark did not include a "protein" among the problematic limitations cited by SPE-Clark, which did include: "DNA expression vector", "viral vector", "oligonucleotide", and "nucleotide analog."

Applicants wish to avoid any misunderstandings and so invite the Examiner to contact Applicants' undersigned attorney at (213) 896-6665 regarding a further interview, if the Examiner believes it would be helpful to the expeditious prosecution of the above-captioned application.

Respectfully submitted,

By: _____
Nisan A. Steinberg, Ph.D.
Reg. No. 40,345

SIDLEY & AUSTIN
555 West Fifth Street
Los Angeles, California 90013
Ofc: 213/ 896-6665
Fax: 213/ 896-6600